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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,052	08/28/2001	Arthur B. Raitano	511582002800	6518

36327 7590 01/30/2006

AGENSYS C/O MORRISON & FOERSTER LLP
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SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER	
BLANCHARD, DAVID J	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/942,052	RAITANO ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *88-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *88-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Exhibit A*.

DETAILED ACTION

1. Claims 1-87 have been cancelled.

Claim 88 has been amended.

2. Claims 88-98 are pending are under examination.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. This Office Action contains New Grounds of Rejections.

Objections/Rejections Withdrawn

5. The rejection of claims 88-98 under 35 U.S.C. 101 because the claimed invention is not supported by a specific and substantial utility or a well-established utility is withdrawn in view of the Rule 1.132 declaration by Dr. Karen Jane Meyrick Morrison filed 10/20/2005.

6. The rejection of claims 88-98 under 35 U.S.C. 112, first paragraph, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention is withdrawn in view of the Rule 1.132 declaration by Dr. Karen Jane Meyrick Morrison filed 10/20/2005.

7. The rejection of claims 88-98 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time

the application was filed, had possession of the claimed invention is withdrawn in view of the amendments to the claims.

8. The rejection of claims 88-98 are rejected under 35 U.S.C. 112, first paragraph, does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims is withdrawn in view of the amendments to the claims.

9. The rejection of claims 88-95 and 97-98 under 35 U.S.C. 102(e) as being anticipated by Tang et al (WO 01/53312) is withdrawn in view of applicant's arguments and the Rule 1.131 Declaration previously submitted on 3/17/2005, which antedates the Tang reference.

10. The rejection of claims 88-95 and 97-98 under 35 U.S.C. 103(a) as being unpatentable over Tang et al (WO 01/53312) in view of Reiter (US Patent 6,261,791 B1) is withdrawn in view of applicant's arguments and the Rule 1.131 Declaration previously submitted on 3/17/2005, which antedates the Tang reference.

New Grounds of Rejections

11. Claims 88-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al (Molecular Microbiology 27(1):171-186, 1998, previously cited on PTO-892 mailed 9/17/04) and in view of Campbell A. M. (Monoclonal Antibody Technology, Elsevier Science Publishers, NY, chapter 1, pages 1-32, 1986, previously cited on PTO-892 mailed 9/17/04) and Queen et al (5,530,101, 6/25/1996, previously cited on PTO-

892 mailed 9/17/04) and Reiter et al (U.S. Patent 6,261,791 B1, 5/25/1999, previously cited on PTO-892 mailed 9/17/04).

The claims are drawn to an antibody or fragment thereof that specifically binds to a protein comprising that amino acid sequence of SEQ ID NO:728, wherein the antibody is a monoclonal, human, humanized, or chimeric antibody and the antibody fragment thereof is a Fab, F(ab)2, Fv or sFv fragment and the antibody is conjugated to a diagnostic or cytotoxic agent and the antibody further comprises a pharmaceutically acceptable carrier.

Williams et al teach the OIP5 polypeptide, which is identical (100% amino acid identity) to the polypeptide of SEQ ID NO:728 (see the alignment attached to the back of this Office Action; Exhibit A) (see Table 2). Williams et al do not specifically teach an antibody that binds the polypeptide of SEQ ID NO:728 (OIP5) or antibody conjugates comprising diagnostic or cytotoxic agents or a pharmaceutically acceptable carrier as instantly claimed. These deficiencies are made up for in the teachings of Campbell and Queen et al and Reiter et al.

Campbell A. M. teaches monoclonal antibodies to polypeptides and states "It is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)" (see page 29).

Queen et al teach human, chimeric, humanized antibodies (see columns 2-3, 11-16). Queen et al teach antibody conjugates comprising cytotoxic agents such as Iodine-131, Yttrium-90, Rhenium-188 and Bismuth-212 or other alpha emitters,

chemotherapeutic agents and cytotoxic proteins such as pseudomonas exotoxin A, ricin, diphtheria toxin and ricin A chain as well as antibody fragments such as Fab (see column 20, lines 1-22). Queen et al also teach pharmaceutical compositions comprising an antibody and a pharmaceutically acceptable carrier (see columns 23-24).

Reiter et al teach monoclonal, chimeric and humanized antibodies and antibody fragments such as Fab, Fab' and F(ab)2 as well as immunoconjugates comprising therapeutic agents such as taxol, etoposide, vincristine, vinblastine, colchicines, actinomycin, diphteria toxin, Pseudomonas exotoxin (PE) A, PE40, abrin and radioisotopes (see entire document, particularly column 14, columns 16-17).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced a monoclonal antibody to the polypeptide of Williams et al by the method of Campbell A. M and produce a chimeric antibody, a humanized antibody, antibody fragments as well as immunoconjugates comprising cytotoxic agents as taught by Queen et al and Reiter et al.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced a monoclonal antibody to the polypeptide of Williams et al by the method of Campbell A. M and to produce a chimeric antibody, a humanized antibody, antibody fragments as well as immunoconjugates comprising cytotoxic agents as taught by Queen et al and Reiter et al because Campbell A. M. teach "it is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)" (see page 29) and Queen et al and Reiter

et al teach chimeric and humanized antibodies as well as immunoconjugates comprising a diagnostic or cytotoxic agent. Thus, it would have been obvious to one of skill in the art at the time the invention was made to have produced a monoclonal antibody to the polypeptide of Williams et al by the method of Campbell A. M and to produce a chimeric antibody, a humanized antibody, antibody fragments as well as immunoconjugates comprising cytotoxic agents as taught by Queen et al and Reiter et al.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusions

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER

Exhibit A

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RESULT 1
OIP5_HUMAN
ID   OIP5_HUMAN     STANDARD;      PRT;   229 AA.
AC   O43482; Q96BX7;
DT   28-FEB-2003 (Rel. 41, Created)
DT   28-FEB-2003 (Rel. 41, Last sequence update)
DT   10-OCT-2003 (Rel. 42, Last annotation update)
DE   Opa-interacting protein 5.
GN   OIP5.
OS   Homo sapiens (Human).
OC   Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
OC   Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
OX   NCBI_TaxID=9606;
RN   [1]
RP   SEQUENCE FROM N.A.
RX   MEDLINE=98125741; PubMed=9466265;
RA   Williams J.M., Chen G.-C., Zhu L., Rest R.F.;
RT   "Using the yeast two-hybrid system to identify human epithelial cell
RT   proteins that bind gonococcal Opa proteins: intracellular gonococci
RT   bind pyruvate kinase via their Opa proteins and require host pyruvate
RT   for growth.";
RL   Mol. Microbiol. 27:171-186(1998).
RN   [2]
RP   SEQUENCE FROM N.A.
RC   TISSUE=Uterus;
RX   MEDLINE=22388257; PubMed=12477932;
RA   Strausberg R.L., Feingold E.A., Grouse L.H., Derge J.G.,
RA   Klausner R.D., Collins F.S., Wagner L., Shenmen C.M., Schuler G.D.,
RA   Altschul S.F., Zeeberg B., Buetow K.H., Schaefer C.F., Bhat N.K.,
RA   Hopkins R.F., Jordan H., Moore T., Max S.I., Wang J., Hsieh F.,
RA   Diatchenko L., Marusina K., Farmer A.A., Rubin G.M., Hong L.,
RA   Stapleton M., Soares M.B., Bonaldo M.F., Casavant T.L., Scheetz T.E.,
RA   Brownstein M.J., Usdin T.B., Toshiyuki S., Carninci P., Prange C.,
RA   Raha S.S., Loquellano N.A., Peters G.J., Abramson R.D., Mullahy S.J.,
RA   Bosak S.A., McEwan P.J., McKernan K.J., Malek J.A., Gunaratne P.H.,
RA   Richards S., Worley K.C., Hale S., Garcia A.M., Gay L.J., Hulyk S.W.,
RA   Villalon D.K., Muzny D.M., Sodergren E.J., Lu X., Gibbs R.A.,
RA   Fahey J., Helton E., Ketteman M., Madan A., Rodrigues S., Sanchez A.,
RA   Whiting M., Madan A., Young A.C., Shevchenko Y., Bouffard G.G.,
RA   Blakesley R.W., Touchman J.W., Green E.D., Dickson M.C.,
RA   Rodriguez A.C., Grimwood J., Schmutz J., Myers R.M.,
RA   Butterfield Y.S.N., Krzywinski M.I., Skalska U., Smailus D.E.,
RA   Schnerch A., Schein J.E., Jones S.J.M., Marra M.A.;
RT   "Generation and initial analysis of more than 15,000 full-length
RT   human and mouse cDNA sequences.";
RL   Proc. Natl. Acad. Sci. U.S.A. 99:16899-16903(2002).
CC   -!- SUBUNIT: Binds outer membrane protein OpaP from Neisseria
CC       gonorrhoeae.
CC   ---------------------------------------------------------------------
CC   This SWISS-PROT entry is copyright. It is produced through a collaboration
CC   between the Swiss Institute of Bioinformatics and the EMBL outstation -
CC   the European Bioinformatics Institute. There are no restrictions on its
CC   use by non-profit institutions as long as its content is in no way
CC   modified and this statement is not removed. Usage by and for commercial
CC   entities requires a license agreement (See http://www.isb-sib.ch/announce/
CC   or send an email to license@isb-sib.ch).
CC   ---------------------------------------------------------------------
DR   EMBL; AF025441; AAC39561.1; ALT_INIT.
DR   EMBL; BC015050; AAH15050.1; -.
DR   MIM; 606020; -.
DR   GO; GO:0005515; F:protein binding; TAS.
DR   GO; GO:0007154; P:cell communication; NAS.
SQ   SEQUENCE   229 AA;  24691 MW;  0EBD4006193A3106 CRC64;

  Query Match             100.0%;  Score 1198;  DB 1;  Length 229;
  Best Local Similarity   100.0%;  Pred. No. 2.7e-104;
  Matches  229;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MAAQPLRHRSRCATPPRGDPCGGTERAIDQASPTTSMEWDTQVVKGSSPLGPAGLGAEEP 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MAAQPLRHRSRCATPPRGDPCGGTERAIDQASPTTSMEWDTQVVKGSSPLGPAGLGAEEP 60

Qy         61 AAGPQLPSWLQPERCAVFQCAQCHAVLADSVHLAWDLSRSLGAVVPSRVTNNVVLEAPPL 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 AAGPQLPSWLQPERCAVFQCAQCHAVLADSVHLAWDLSRSLGAVVPSRVTNNVVLEAPPL 120

Qy        121 VGIEGSLKGSTYNLLPCGSCGIPVGPHLYSTHAALAALRGHPCLSSDKMVCYLLKTKAIV 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 VGIEGSLKGSTYNLLPCGSCGIPVGPHLYSTHAALAALRGHPCLSSDKMVCYLLKTKAIV 180

Qy        181 NASEMDIQNVPLSEKIAELKEKIVLTHNRLKSLMKILSEVTPDQSKPEN 229
              |||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 NASEMDIQNVPLSEKIAELKEKIVLTHNRLKSLMKILSEVTPDQSKPEN 229
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